

REMARKS

Review and reconsideration of the Office Action dated September 01, 2005, is respectfully requested in view of the following amendments and the following remarks.

Applicants are pleased with the Examiner's indication that Claims 28-30, 41, and 47 are allowed. Applicants believe that for the reasons set forth below, the remaining claims are also allowed.

The Claims have been amended. Support for the claim amendment can be found on paragraphs [00030] to [00040] of the specification as originally filed.

No new matter has been added to the claims by the present amendment.

Office Action

Turning now to the Office Action, the paragraphing of the Examiner is adopted.

Information Disclosure Statement

The information disclosure statement filed 8/16/2004 has been considered.

Claims Rejections - Anticipation

The Examiner rejects Claims 23, 24, 25, 31, and 32 under 35 U.S.C. 102(b) as being anticipated by Tokita et al (US 4584991).

The position of the Examiner can be found on page 2 of the Office Action.

Applicants respectfully traverse.

In order to anticipate a claim, the reference must disclose all the elements of the claim.

Applicants reviewed the cited reference and note that the Tokita reference is not directed to a radiation source for **endovascular** radiation treatment. Furthermore, Applicants note that the reference fails to teach that the at least one deflection site is located over a portion of the internal lumen of the container where the two end caps of treating elements are opposing faced to each other.

Applicants note that Tokita does not disclose a radiation source for **endovascular radiation treatment**. The reference teaches a solid carrier for applying therapeutic radiation internally via a bodily orifice (col. 1, line 10) such as, a nasal or ear channel (col. 4, line 20), or the uterus (col. 5, line 11). The carrier comprises channels (26) into which radiation sources (28) are inserted. The focus of Tokita is on the solid carrier, and the radiation sources (28) are only briefly described (col. 4, lines 49-63).

The radiation sources according to Tokita comprises cylindrical sleeves (30) strung on a wire (32) with a plastic coating (34) that maintains the spacing of the sleeves, the whole being inserted into a plastic tube (36). The radiation sources are adapted for insertion into the smooth, hard, wide-radius, solid curved channels of the carrier (**Fig. 1**).

The carrier taught by Tokita is adapted for insertion into bodily orifices that have a significantly larger diameter than a typical blood vessel, and the radiation source contemplated by Tokita (12, 14) would be understood by one of ordinary skill to have much larger dimensions than a radiation source suitable for endovascular radiation treatment.

Furthermore, Applicants reviewed the reference and note that it fails to teach or suggest that the at least one deflection site is located over a portion of the internal lumen of the container where the two end caps of treating elements are opposing faced to each other.

In addition, Applicants note that there is no teaching or suggestion that the elongated container is flexible. (Claim 25)

The flexible elongated container of the present invention is a self-supported structure with the dual function of holding the at least two seeds together in a single radiation source and, simultaneously, providing sufficient flexibility of the source to render the source useful in endovascular radiation treatment.

In contrast, the radiation source of Tokita comprises cylindrical sleeves strung on a wire-like member enclosed by a plastic **coating** (34). The coating disclosed by Tokita exclusively serves to retain the spacing of the cylindrical sleeves (30) (col. 4, lines 58-59) and is not taught as holding the entire source together, a function that is instead fulfilled by the wire-like element (32). Tokita, therefore, does not teach an element that is equivalent to the flexible elongated container of the present invention.

The elongated container of the present invention is a self-supporting structure ("container") as distinct from a mere coating as taught by the cited reference.

Thus, Tokita, therefore, fails to disclose all of the elements of the rejected claims, and cannot anticipate them.

In view of the above remarks, Applicants respectfully request reconsideration and withdrawal of the rejection.

Claims Rejections - (Obviousness)

The Examiner rejects Claims 36 and 37 under 35 U.S.C. 103(a) as being obvious over Tokita et al (US 4584991).

The position of the Examiner can be found on page 2 of the Office Action.

Applicants respectfully traverse for the same reasons as set forth in the previous paragraph and the following remarks.

Claims 36-37 are novel in view of their dependency with novel Claim 23.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

Claims Rejections - (Obviousness)

The Examiner rejects Claims 23-27, 31, 34-40, 42-46, and 48-52 under 35 U.S.C. 103(a) as being obvious over Klein (5,863,284) in view of Good (5,342,283).

Applicants respectfully traverse.

Neither Klein nor Good taken alone or in combination teach the present invention because all of them fail to teach that the at least one deflection site is located over a portion of the internal lumen of the container where the two end caps of treating elements are opposing faced to each other.

Applicants reviewed the Klein reference and note that the reference teaches a catheter system comprising an expansion member which readily expands the radioactive element away from the catheter body and toward a vessel wall.

In addition, Applicants note that the Examiner relies on Figures 36-37 to show the teaching of a radiation source with seeds. Applicants respectfully point out to the Examiner that Figures 36 and 37 of the reference show only the individual seeds which are incorporated in combination into a large device, namely expandable member, specifically an elastomeric balloon. See Claim 18 of the reference. Only this entire device forms the radiation source which is completely different from the radiation source according to the present invention.

The Examiner cited the Good reference to show spherical sources including layers to confine the radiation emitting layer to protect, seal, identify or filter the radiation (column 40, lines 48-66).

According to the Examiner it would have been obvious to one of ordinary skills in the art at the time the invention was made to use the radiation elements of Good for the spheres taught by Klein in order to provide a protective containment layer to protect, seal, identify or filter the radiation.

Applicants reviewed the Good reference and note that the reference teaches an intracavetary radiation-emitting capsule 30 having a plurality of radiation emitting microspheres, a stainless steel tube and a weld (Column 54, line 46 -end). The stainless steel tube provides shielding **but not the required flexibility** afforded by the inventive **deflection sites** of the present invention.

Applicants respectfully point out to the Examiner that the Examiner has an initial duty to supply a factual basis for each rejection, including obviousness rejections. The courts have interpreted this duty as placing on the Examiner the burden of presenting a *prima facie* (on first view) case of obviousness. Thus, in the Office action, the Examiner must not only assert that a claimed invention is obvious, he must provide to the applicant "such information and references as may be useful in judging of the propriety of continuing the prosecution of his application" (35 USC 132). The MPEP describes the information that must be provided by the Examiner as follows: "(A) the relevant teachings of the prior art relied upon, preferably with reference to the relevant column or page number(s) and line number(s) where appropriate, (B) the difference or differences in the claim over the applied reference(s), (C) the proposed modification of the applied reference(s) necessary to arrive at the claimed subject matter, and (D) an explanation why one of ordinary skill in the art at the time the invention was made would have been motivated to make the proposed modification" (MPEP 706.02(j)).

Applicants respectfully point out to the Examiner that a reason, suggestion or motivation for combining the teachings of the references to produce the claimed invention **must be present in the prior art**, and the resulting combination or modification of the prior art would render the claimed invention obvious to a person having ordinary skill in the art. In the present case the Klein reference fails to teach or suggest the modification as suggested by the Examiner. Furthermore, the teaching of Good were available for five years to a person of ordinary skills in the art at the time the Klein reference was made; thus, if the modification was so obvious, why Klein did not consider it?

In addition, 103 requires that the prior art as a whole contain some implicit or explicit reason, suggestion or motivation for a person of ordinary skill (having no knowledge of the claimed invention) to combine or modify the references in the way proposed by the Examiner. Just because references can be combined or modified does not render the proposed combination obvious, unless the prior art also suggests the desirability of the combination (MPEP 2143.01). A reasonable expectation of success of the proposed combination or modification is also required (MPEP 2143.02). In the present case, the Examiner is making the very human mistake of using impermissible hindsight (recognizing the advisability to combine the references only after the inventor has claimed the combination) as the motivation to combine the references.

Accordingly, the withdrawal of the rejection is respectfully requested.

Claims Rejections - (Obviousness)

The Examiner rejects Claims 32 and 33 under 35 U.S.C. 103(a) as being obvious over Klein (5,863,284) in view of Good (5,342,283) and further in view of Cutrer (5,997,463).

The position of the Examiner can be found on pages 3-7 of the Office Action.

Applicants respectfully traverse for the same reasons as set forth in the previous paragraph and the following remarks.

Neither Klein, Good, nor Cutrer taken alone or in combination teach the present invention because all of them fail to teach that the at least one deflection site is located over a portion of the internal lumen of the container where the two end caps of treating elements are opposing faced to each other.

Accordingly, the withdrawal of the rejection is respectfully requested.

Allowable Subject Matter

The Examiner indicated that Claims 28-30, 41 and 47 are allowed.

Applicants are pleased with the indication.

Favorable consideration and early issuance of the Notice of Allowance are respectfully requested. Should further issues remain prior to allowance, the Examiner is respectfully requested to contact the undersigned at the indicated telephone number.

Respectfully submitted,



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Date: **January 3, 2006**



CERTIFICATE OF MAILING AND AUTHORIZATION TO CHARGE

I hereby certify that a copy of the foregoing AMENDMENT E for U.S. Application No. 10/018,623 filed December 18, 2001, was deposited in first class U.S. mail, postage prepaid, addressed: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on **January 3, 2006**.

The Commissioner is hereby authorized to charge any additional fees that may be required at any time during the prosecution of this application, except for the issue fee, without specific authorization, or credit any overpayment, to Deposit Account No. 16-0877.

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